AN ACT relating to pharmacy benefit management.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

- →SECTION 1. A NEW SECTION OF SUBTITLE 9 OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:
- (1) (a) In order to conduct business in this state, a pharmacy benefit manager shall first obtain a license from the commissioner. The license shall be in lieu of an administrator's license as required by KRS 304.9-052.
  - (b) A licensed pharmacy benefit manager performing utilization review, as defined in KRS 304.17A-600, shall be registered as a private review agent in accordance with KRS 304.17A-607.
- (2) A pharmacy benefit manager seeking a license shall apply to the commissioner in writing on a form provided by the department. The application form shall state the name, address, official position, and professional qualifications of each individual responsible for the conduct of affairs of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association, and any other person who exercises control or influence over the affairs of the pharmacy benefit manager and the name and address of the applicant's agent for service of process in this state.
- (3) Each application for a license shall be accompanied by a nonrefundable fee of one thousand dollars (\$1,000) and evidence of a surety bond in an amount of one million dollars (\$1,000,000).
- (4) Any person acting as a pharmacy benefit manager on the effective date of this

  Act and who is required to obtain a license under subsection (1) of this section,

  shall obtain a license from the commissioner not later than January 1, 2017, in

  order to continue to do business in this state.

- (5) All licenses issued under this section shall expire annually on December 31.
- (6) Any pharmacy benefit manager seeking to renew a license shall apply to the commissioner in writing on a form provided by the department. The application shall be accompanied by a nonrefundable fee of one thousand dollars (\$1,000).

  Any late payment of the fee shall include a penalty fee of five hundred dollars (\$500).
  - → Section 2. KRS 304.17A-161 is amended to read as follows:

As used in this section, *Sections 1, 3, 4, 5, and 6 of this Act*, and KRS 304.17A-162, unless the context requires otherwise:

- (1) "Contracted pharmacy" or "pharmacy" means a pharmacy located in Kentucky participating in the network of a pharmacy benefit manager through a direct contract or through a contract with a pharmacy services administration organization or group purchasing organization;
- (2) "Drug product reimbursement" means the amount paid by a pharmacy benefit manager to a contracted pharmacy for the cost of the drug dispensed to a patient and does not include a dispensing or professional fee; [and]
- (3) "Maximum allowable cost" means the maximum amount that a pharmacy
  benefit manager will reimburse a pharmacy for the cost of a generic drug and
  does not include a dispensing or professional fee; and
- (4) "Pharmacy benefit manager" means an entity that [contracts with pharmacies] on behalf of a health benefit plan sponsor, state agency, insurer, managed care organization providing services under KRS Chapter 205, or other third-party payor:
  - (a) Contracts directly or indirectly with pharmacies to provide prescription drugs to individuals;
  - (b) Administers a prescription drug benefit;
  - (c) Processes or pays pharmacy claims;

- (d) Creates or updates prescription drug formularies;
- (e) Makes or assists in making prior authorization determinations on prescription drugs;
- (f) Administers rebates on prescription drugs; or
- (g) Establishes a pharmacy network [to provide pharmacy health benefit services or administration].
- → Section 3. KRS 304.17A-162 is amended to read as follows:
- (1) <u>A pharmacy benefit manager shall</u>[All contracts between a pharmacy benefit manager and a contracted pharmacy shall include]:
  - (a) <u>Identify to contracted pharmacies</u> the sources used by the pharmacy benefit manager to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by the pharmacy benefit manager; *and*
  - (b) <u>Establish</u> a process <u>for contracted pharmacies</u> to appeal[, investigate,] and resolve disputes regarding the maximum allowable cost pricing. The process shall include the following provisions:
    - 1. The right to appeal shall be limited to sixty (60) days following the initial claim;
    - 2. The appeal shall be investigated and resolved <u>by the pharmacy benefit</u>

      <u>manager</u> within ten (10) <u>calendar</u> days;<del>[ and]</del>
    - 3. The pharmacy benefit manager shall respond to all appeals on a form approved by the department;
    - 4. If the appeal is denied, the pharmacy benefit manager shall provide the reason for the denial and identify the national drug code of a drug product and source where it [that] may be purchased from a wholesaler by contracted pharmacies at a price at or below the maximum allowable cost; and

- this subsection, the pharmacy benefit manager shall adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that pharmacy benefit manager that fill a prescription for patients covered under the same health benefit plan in the next payment cycle. The adjustment shall be effective from the date of service in filling a prescription for a patient, and the pharmacy benefit manager shall provide retroactive reimbursement to the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan in the next payment cycle.
- [(c) Within one (1) year from June 25, 2013, a process to provide for retroactive reimbursements.]
- (2) If a price update is warranted as a result of an appeal granted under subsection

  (1) of this section, the pharmacy benefit manager shall:
  - (a) Make the change in maximum allowable cost;
  - (b) Permit the appealing pharmacy and other contracted pharmacies in the

    network that filled prescriptions for all patients covered under health

    benefit plans using the same network to reverse and resubmit the claim in

    question; and
  - (c) Make the maximum allowable cost change effective for each contracted

    pharmacy in the network that fills prescriptions for all patients covered

    under health benefit plans using the same network.
- (3) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall:
  - (a) Make available to all contracted pharmacies [Include in the contract with the

- pharmacy] information identifying the national drug pricing compendia or sources used to obtain the drug price data <u>in a manner established by administrative regulations promulgated by the department</u>;
- (b) Make available to <u>all contracted pharmacies in a manner established by</u>

  <u>administrative regulations promulgated by the department</u>[a contracted pharmacy] the <u>comprehensive list of</u> drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug;
- (c) <u>Make available to the department, upon request, its methodology used in calculating maximum allowable cost. The information shall be considered confidential;</u>
- (d) Review and make necessary adjustments to the maximum allowable cost for every drug at least every <u>seven (7) calendar</u>[fourteen (14)] days <u>and shall</u> <u>immediately utilize the updated maximum allowable cost in calculating the payments made to all contracted pharmacies;[and]</u>
- (e) [(d)] Make available to all contracted pharmacies in a manner established

  by administrative regulations promulgated by the department [a contracted pharmacy] weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug; and
- A-rated in the most recent version of the United States Food and Drug

  Administration Approved Drug Products with Therapeutic Equivalence

  Evaluations, also known as the Orange Book, are generally available for purchase by pharmacies in Kentucky from national or regional wholesalers licensed by the Kentucky Board of Pharmacy, and are not obsolete, temporarily unavailable, or listed on a drug shortage list.
- → SECTION 4. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

- (1) Upon receipt of a completed application, evidence of a surety bond, and fee, the commissioner shall make an investigation of each applicant and shall issue a license if the applicant is qualified in accordance with this section and Sections 1, 3, 5, and 6 of this Act.
- (2) The commissioner may require additional information or submissions from applicants and may obtain any documents or information reasonably necessary to verify the information contained in the application.
- (3) The commissioner may suspend, revoke, or refuse to issue or renew any license in accordance with KRS 304.9-440.
- (4) The commissioner may make determinations on the length of suspension for an applicant, not to exceed twenty-four (24) months. However, the licensee may have the alternative, subject to the approval of the commissioner, to pay in lieu of part or all of the days of any suspension period a sum of one thousand dollars (\$1,000) per day not to exceed two hundred fifty thousand dollars (\$250,000).
- (5) If the commissioner's denial or revocation is sustained after a hearing, an applicant may make a new application not less than one (1) full year after the date on which a denial or revocation was sustained.
- (6) The department shall adopt administrative regulations in accordance with KRS

  Chapter 13A to implement and enforce the provisions of this section and Sections

  1, 3, 5, and 6 of this Act. The administrative regulations shall specify the contents of the application form and any other form or report required.
- (7) The department may impose a fee upon pharmacy benefit managers in addition to a license fee to cover the costs of enforcement of this section and Sections 1, 3, 5, and 6 of this Act, including fees to cover the cost of:
  - (a) Salaries and benefits paid to the personnel of the department engaged in the enforcement;
  - (b) Reasonable technology costs related to the enforcement process.

Technology costs shall include the actual cost of software and hardware utilized in the enforcement process and the cost of training personnel in the proper use of the software or hardware; and

- (c) Reasonable education and training costs incurred by the state to maintain the proficiency and competence of the enforcing personnel.
- →SECTION 5. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

Pharmacy benefit managers shall be subject to this subtitle and to the provisions of KRS Chapter 304 Subtitles 1, 2, 3, 4, 9, 12, 14, 17, 17C, 18, 25, 27, 32, 38, and 99 to the extent applicable and not in conflict with the expressed provisions of this subtitle.

→SECTION 6. A NEW SECTION OF KRS CHAPTER 205 IS CREATED TO READ AS FOLLOWS:

A pharmacy benefit manager contracted with a managed care organization that provides Medicaid benefits pursuant to this chapter shall comply with the provisions of this section and Sections 1, 3, 4, and 5, of this Act.